K121140

5. 510(k) Summary– PROLYTE Electrolyte Analyzer Na+/K+/Cl-/Li+

(1) Submitted by:

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AUG 2 2 2012

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(3) Summary Prepared:

April 13, 2012

(4) Device Trade Name:

PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$

(5) Regulatory Information:

Description	CFR Section	Device Class	Product Code
Sodium Test System	862.1665	Class II	JGS
Potassium Test System	862.1600	Class II	CEM
Chloride Test System	862.1170	Class II	CGZ
Lithium Test System	862.3560	Class II	JIH

Panel: Chemistry, 75

(6) Predicate Device:

Description	510(k)	Analytes
GEMLTYE Electrolyte Analyzer $Na^+/K^+/Cl^-$ Ca^{2+}/Li^+	K082462	Sodium, Potassium, Chloride, Calcium, Lithium

Statement of Technology Characteristics of the Device Compared to Predicate Device:

Operating Principle	Predicate Device	PROLYTE
Potentiometric Na^+, K^+, Cl^-, Li^+ Electrodes	K070104	SAME

(7) Device Description:

The PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$ is intended to be a direct replacement for the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-$ (k102959). The PROLYTE Na^+, K^+, Cl^-/Li^+ Electrolyte Analyzer has all the features of the Diamond Prolyte Electrolyte Analyzer $Na^+/K^+/Cl^-$ (k102959), with the added feature that the Cl^- ISE sensor may be replaced by a Li^+ ISE sensor by the end-user.

The PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$ is designed for clinical laboratory use by laboratory professionals to assess the levels of Sodium, Potassium, Chloride and Lithium found in whole blood, plasma, and serum of patients. Sodium, Potassium, and Chloride are also assessed in urine of patients. The analysis is performed *in-vitro*, and neither the analyzer nor any of its components come in contact with the patient.

This bench top analyzer is used by trained laboratory technicians in clinical laboratories to aid in the diagnosis and treatment of patients with electrolyte imbalance as well for the monitoring drug levels in those

patents taking Lithium. These locations routinely conform to CLIA regulations, and conduct daily quality control programs.
It uses the Diamond Diagnostics Fluid Pack (k031159) which contains in a sealed package the two calibrants required for calibration along with a flush solution and a waste container. The analyzer can be programmed to self-calibrate at set intervals or on request. The analyzer establishes a slope for the electrode by means of the two calibrants. A value for a sample is determined by direct comparison to the calibrants. Mission Controls (k033063) are the recommended quality control material to be used daily.

(8) Intended Use:

a. Intended use(s):

The PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li$ is designed for clinical laboratory use by laboratory professionals to assess the levels of Sodium, Potassium, Chloride and Lithium found in whole blood, serum, plasma, and urine of patients. The analysis is performed *in-vitro*, and neither the analyzer nor any of its components come in contact with the patient.

This analyzer is used by trained laboratory technicians in clinical laboratories to aid in the diagnosis and treatment of patients with electrolyte imbalance as well as monitoring the lithium levels for those patients taking lithium. These locations routinely conform to CLIA regulations, and conduct daily quality control programs.

b. Indication(s) for use:

The PROLYTE is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride and lithium in whole blood, plasma, serum, and urine samples.

The PROLYTE Sodium Assay is intended to measure sodium in whole blood, plasma, serum, and urine on the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li$. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The PROLYTE Potassium Assay is intended to measure potassium in whole blood, plasma, serum, and urine on the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li$. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

The PROLYTE Chloride Assay is intended to measure the level of chloride in whole blood, plasma, serum, and urine on the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li$. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The PROLYTE Lithium test system is intended to measure lithium (from the drug lithium carbonate) in whole blood, plasma, or serum on the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li$. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

It is For In Vitro Diagnostic Use.

(9) Technological Characteristics of the Device:

Measurement Principles:
The principles of measurement used in the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$ are identical to those principles existing in the predicate electrolyte analyzers GEMLYTE (k082462) and PROLYTE (k102959).

The PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$ measures sodium, potassium, chloride and lithium in whole blood, serum, plasma, and urine (except lithium), using ion selective electrode technology. The sodium electrode contains a glass tube, specially formulated to be sensitive to sodium ions. The potassium and lithium electrodes incorporate a neutral carrier ionophore membrane. The chloride

contains an ionophore covalently bound to a substrate which is sensitive to negatively charged ions. The potential of each electrode is measured relative to a fixed, stable reference established by a silver/silver chloride electrode in concentrated salt solution. The measured potential varies with the concentration of the ion sensed by the electrode.

Comparison to Predicate Device:
The PROLYTE Na^+, K^+, Cl^-, Li^+ Electrolyte Analyzer is an analyzer that has all the features of the Diamond Prolyte Na^+, K^+, Cl^- Electrolyte Analyzer (k102959), but the Cl^- ISE sensor may be replaced by a Li^+ ISE sensor by the end-user. This is similar to the second predicate device, GEMLYTE Na^+, K^+, Cl^-, Ca^{2+}, Li^+ Electrolyte Analyzer (k082462) where the Cl^- ISE sensor may be replaced by a Li^+ or Ca^{2+} ISE sensor by the end-user.

The default configuration of the PROLYTE Na^+, K^+, Cl^-, Li^+ Electrolyte Analyzer is Na^+ - K^+ - Cl^-. The user can select Li^+ under the Operator Functions menu in the same manner as the selection is made in the predicate, GEMLYTE. Moreover, the Fluid Pack (k031159) used for calibration, flushing and waste storage is the same as the predicate PROLYTE device and the candidate device. To simplify operation of the PROLYTE, the menu structure was modified to be similar to SMARLTYE where there is a single menu level. The predicate PROLYTE had a Main Menu that could step into a Second Menu for certain functions.

Comparison Table below shows primary similarities and differences between the candidate device and the predicate devices.

Comparison to Predicate Device		
Item	**CANDIDATE DEVICE**	**PREDICATE**
Trade/proprietary name	PROLYTE ELECTROLYTE ANALYZER	GEMLYTE
Model number	Na K Cl Li	Na K Cl Ca Li
Manufacturer	Diamond Diagnostics Corp	Diamond Diagnostics Corp
510(k)/PMA reference number		K082462
Intended use	Sodium, Potassium, Chloride, Lithium determination	Also has Calcium
Sample Type	Blood, serum, plasma, urine	Same
Measurement Principle	Ion Selective Electrodes	Same
Analysis time, blood	59 sec	57 sec
Analysis time, Urine	69 sec	57
Measurement Range, Blood		
Na	45 - 205 mEq/L	40 - 200 mEq/L
K	1.5 - 11 mEq/L	1.7 - 15 mEq/L
Cl	45 - 205 mEq/L	50 - 200 mEq/L
Li	0.15 - 5.0 mEq/L	0.2 - 5.5 mEq/L
Measurement Range, Urine		
Na	25 - 1020 mEq/L	3 - 300 mEq/L
K	10 - 505 mEq/L	5 - 120 mEq/L
Cl	25 - 505 mEq/L	15 - 300 mEq/L
Sodium: Blood, Plasma, Serum Precision		
Expected, within run CV	= 1 %	Same
Expected, between run CV	= 2 %	Same
Potassium: Blood, Plasma, Serum Precision		
Expected, within run CV	= 2 %	≤ 1.5 %
Expected, between run CV	= 2.5 %	≤ 3 %
Chloride: Blood, Plasma, Serum Precision		
Expected, within run CV	= 2 %	≤ 1 %
Expected, between run CV	= 2.5 %	≤ 3 %
Lithium: Blood, Plasma, Serum Precision		
Expected, within run sd	≤ 0.03	Same
Expected, between run sd	≤ 0.09	Same
Sodium: Urine Precision		
Expected, within run CV	= 2.5 %	≤ 5 %
Expected, between run CV	= 5 %	≤ 5 %
Potassium: Urine Precision		
Expected, within run CV	= 2.5 %	≤ 5 %
Expected, between run CV	= 5 %	≤ 5 %
Chloride: Urine Precision		
Expected, within run CV	= 2.5 %	≤ 5 %
Expected, between run CV	= 5 %	≤ 5 %
Calibration	Automatic and on Demand	Same
Reagent Pack	800 ml Fluid Pack	350 ml Fluid Pack
QC storage	LEVELS 1, 2, 3 (500 each)	QC Levels 1, 2, 3 results, total 35
Sample Results Storage	1000	Last Sample
Sample Data Recall	Recall by Date and Sample ID added	Last Sample
Output	32 character, 2 line alphanumeric display	Same
	40 column thermal printer	16 Column thermal printer
	RS-232 Serial port	Same
Power Requirements	100-240V 50/60Hz 1.6 A	Same
Microcontroller processor	Microchip dsPIC33FJ256	Freescale 68HC16
Program Flow	Single level menu structure	Single level menu structure

(10) Summary of non-clinical tests:

Precision – Sodium, Potassium and Chloride in whole blood, plasma, serum and urine were previously cleared (K105929).

Lithium precision was calculated with results from five whole blood, plasma and serum samples. The sample concentrations were at the reportable limits as well as low and high end of reference ranges and near the mid point range. For within run precision, 30 replicates of each sample without calibration between measurements were collected. The replicates were run consecutively in one day

Total precision was determined by measuring the plasma and serum samples twice each morning and twice each afternoon for ten days resulting in 40 replicates. Whole blood total precision was conducted in a single day due to the instability of blood. For whole blood, four groups of 10 replicates separated by a calibration was collected. Lithium demonstrated precision within the limits defined below in the reference range, 0.3 to 2.0 mEq/L..

	Within Run	Run to Run	
Li^+	S.D. ≤ 0.03	≤ 0.09	(0.3 – 2.0 mEq/L)

The tables below show the precision results.

Whole Blood, mEq/L

WITHIN RUN	V Low	Low	Mid	High	V High
Mean	0.216	0.607	1.035	1.727	4.153
SD	**0.010**	**0.008**	**0.009**	**0.010**	**0.030**
%CV	4.76	1.24	0.82	0.57	0.72
N	30	30	30	30	30
Spec, BLD	0.03	0.03	0.03	0.03	0.03
PASS/FAIL	P	P	P	P	P

RUN TO RUN	V Low	Low	Mid	High	V High
Mean	0.227	0.607	1.031	1.740	4.171
SD	**0.014**	**0.009**	**0.010**	**0.009**	**0.036**
%CV	6.31	1.56	0.95	0.52	0.85
N	40	40	40	40	40
Spec, BLD	0.09	0.09	0.09	0.09	0.09
PASS/FAIL	P	P	P	P	P

Plasma, mEq/L

Within Run	V Low	Low	Mid	High	V High
Mean	0.32130	0.62003	1.09253	2.29560	4.41513
SD	**0.00531**	**0.00482**	**0.00308**	**0.01336**	**0.06310**
%CV	1.65	0.78	0.28	0.58	1.43
N	30	30	30	30	30
Spec, BLD	0.03	0.03	0.03	0.03	0.03
PASS/FAIL	P	P	P	P	F

Run to Run	V Low	Low	Mid	High	V High
Mean	0.32668	0.62789	1.09495	2.28523	4.37893
SD	**0.01462**	**0.00682**	**0.00666**	**0.02444**	**0.06651**
%CV	4.47	1.09	0.61	1.07	1.52
N	40	44	40	40	41
Spec, BLD	0.09	0.09	0.09	0.09	0.09
PASS/FAIL	P	P	P	P	P

Serum, mEq/L

Within Run	V Low	Low	Mid	High	V High
Mean	0.25563	0.59367	1.05813	1.99907	4.30820
SD	0.00844	0.00646	0.00445	0.01166	0.04239
%CV	3.30	1.09	0.42	0.58	0.98
N	30	30	30	30	30
Spec, BLD	0.03	0.03	0.03	0.03	0.03
PASS/FAIL	P	P	P	P	F

Run to Run	V Low	Low	Mid	High	V High
Mean	0.2928	0.5956	1.0610	2.0073	4.3562
SD	0.0280	0.0164	0.0074	0.0425	0.0824
%CV	9.56	2.76	0.70	2.12	1.89
N	40	40	40	40	40
Spec, BLD	0.09	0.09	0.09	0.09	0.09
PASS/FAIL	P	P	P	P	P

Linearity - Sodium, Potassium and Chloride in whole blood, plasma, serum and urine were previously cleared (K105929).

Linearity was evaluated by preparing stock solution with a high concentration of Li^+ in whole blood, plasma, and serum. The stock was diluted serially (20%) to concentrations across the measuring ranges of each analyte and matrix. Linear regression was performed using expected values based on the stock sample dilution. The results are shown below.

Lithium Linearity, Measured compared to Expected Values, mEq/L

Parameter	Slope	Intercept	R^2	Range	n
Whole blood	0.9854	-0.0285	0.9979	0.15 – 5.5	100
Plasma	0.9985	-0.0315	0.9997	0.1 - 5.9	38
Serum	1.0068	0.019	0.9998	0.1 – 5.7	44

The linearity studies support the following reportable range.

Measuring Range Whole Blood, Plasma, Serum	Li^+: 0.15 – 5.0 mEq/L

(11) Summary of clinical tests submitted with the pre-market notification for the device.

Sodium, Potassium and Chloride in whole blood, plasma, serum and urine were previously cleared (K105929).

Method comparison to predicate device was performed with whole blood, plasma, serum patient samples. Some samples were spiked or diluted to fully span the claimed measuring range. The results are summarized below.

PROLYTE Li versus Predicate, GEMLYTE (k082462) in Various Matrices, Lithium mEq/L

Parameter	Slope	Intercept	R^2	Range	n
Whole Blood	1.0096	0.0719	0.9947	0.15 – 5.0	94
Plasma	0.9806	0.1292	0.9971	0.16 - 5.0	100
Serum	0.9977	0.0133	0.9881	0.17 - 4.7	91

The method comparison studies support correlation in the reportable range.

Measuring Range Whole Blood, Plasma, Serum	Li^+: 0.15 – 5.0 mEq/L

(12) Conclusions drawn from the clinical and non-clinical testing.

Analysis of the comparative measurement presented in the 510(k) for this device, together with the linearity and precision data collected during these clinical and non-clinical trails demonstrates that the Diamond Diagnostics *PROLYTE* Electrolyte Analyzer lithium test system is safe, effective and substantially equivalent to its predicate device, the GEMLYTE (K082462).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Diamond Diagnostics, Inc.
c/o Kathy Cruz, Quality Assurance Manager
333 Fiske St.
Holliston, MA 01746

AUG 2 2 2012

Re: k121140
Trade Name: PROLYTE Electrolyte Analyzer Na+/K+/Cl-/Li+
Regulation Number: 21 CFR §862.3560
Regulation Name: Lithium test system
Regulatory Class: Class II
Product Codes: JIH, JGS, CEM, CGZ
Dated: July 24, 2012
Received: July 31, 2012

Dear Ms. Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510 (k) Number (if known): K121140

Device Name: PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$

Indication For Use:

The PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$ is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride and lithium in whole blood, plasma, and serum. Sodium, potassium, and chloride can be measured in urine samples.

The PROLYTE Sodium Assay is intended to measure sodium in whole blood, plasma, serum, and urine on the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The PROLYTE Potassium Assay is intended to measure potassium in whole blood, plasma, serum, and urine on the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

The PROLYTE Chloride Assay is intended to measure the level of chloride in whole blood, plasma, serum, and urine on the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The PROLYTE Lithium test system is intended to measure lithium (from the drug lithium carbonate) in whole blood, plasma, or serum on the PROLYTE Electrolyte Analyzer $Na^+/K^+/Cl^-/Li^+$. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121140